Health Care Providers and Fraud Investigations: What Can You Do When the Government Changes the Rules in the Middle of the Game?

Gordon E. Rountree Jr.
Sullivan, Stolier & Resor

Follow this and additional works at: http://lawecommons.luc.edu/annals
Part of the Health Law and Policy Commons

Recommended Citation
Available at: http://lawecommons.luc.edu/annals/vol8/iss1/4

This Article is brought to you for free and open access by LAW eCommons. It has been accepted for inclusion in Annals of Health Law by an authorized administrator of LAW eCommons. For more information, please contact law-library@luc.edu.
Health Care Providers and Fraud Investigations: What Can You Do When the Government Changes the Rules in the Middle of the Game?

Gordon E. Rountree, Jr.*

INTRODUCTION

In fiscal year 1997, the federal government collected $1.1 billion in criminal fines, civil judgments, and settlements as a result of health care fraud enforcement efforts.¹ Health care providers have good reason to feel pressured as the government continues to increase² its effort to recoup the estimated $100 billion lost annually to health care fraud.³ Health care fraud has attracted significant national attention since 1994 when Attorney General Janet Reno identified it as the Department of Justice’s highest priority, behind violent crime.⁴ From the perspective of providers, the situation is not expected to improve any time soon. On January 23, 1998, President Clinton announced that his administration’s fiscal 1999 budget would include ten new anti-fraud initiatives, including a plan to double the number of provider audits conducted annually by the government.⁵

But has the government gone too far in its aggressive efforts to investigate and prosecute those who commit health care

* Gordon E. Rountree, Jr., is an associate with the law firm of Sullivan, Stolier & Resor, in New Orleans, Louisiana. He received his Bachelor of Arts from Hampden-Sydney College and his Juris Doctor, cum laude, from Tulane University, School of Law, and his Master of Laws (Health Law) from Loyola University Chicago School of Law. The author thanks Professor Joan Krause, of Loyola University Chicago School of Law, for her editorial review and comments, and Mary Smith, administrative assistant of Sullivan, Stolier & Resor, for her valuable assistance during the editorial and revision process.

fraud? The government's recent fraud probes have not been directed at individual providers with questionable billing habits, but rather at entire sectors of the health care industry, such as Physicians at Teaching Hospitals ("PATH"), independent clinical laboratories ("LabScam"), hospitals ("Transfer/Discharge" and "DRG Upcoding"), and hospital outpatient labs ("Operation Bad Bundle").6 Another probe, "Operation Re-store Trust," is an example of a multi-prong attack on health care fraud. This three-year-old initiative initially targeted fraud in five states in the nursing home, home health, and durable medical equipment industries. Due to its success, the initiative was expanded in 1997 to include twelve additional states, and its focus was broadened to include independent physiological labs, psychiatric hospitals, and partial hospitalization.7 In addition to catching providers who intentionally try to defraud the government, this dragnet approach is also bound to snare innocent or confused providers, who may have valid justifications and defenses for their billing practices.

As a result of these new fraud initiatives, the government appears to have pursued national fraud investigations against providers based on practices that the government had either explicitly approved of or tacitly accepted in years past.8 When this happens, providers are put in a difficult position. A provider may have billed and received payment from Medicare based upon a fiscal intermediary's or carrier's advice (or silence) for a number of years. When faced with allegations of billing fraud, particularly a demand for penalties under the False Claims Act, what is the provider to do?

This article addresses federal government health care fraud investigations and focuses on the options available to those health care providers being investigated because of practices instituted or continued as a result of implicit or explicit advice from the federal government. Three possible provider re-

6. See Himali, supra note 2, at 1767-68.
7. See Administration Expands Health Fraud Effort to 12 More States, 6 BNA's HEALTH L. REP. 807 (May 22, 1997); see also HCFA, Medical Savings Captured Under Two-Year Project, IG Report Finds, 5 BNA'S HEALTH L. REP. 1829 (Dec. 19, 1996); see generally IG Launches Multi-Prong Attack in Fraud in Nursing Homes, Home Health Agencies, 4 BNA'S HEALTH L. REP. 718 (May 11, 1995).
The responses include: (1) lobbying the government for relief; (2) suing the government; or (3) waiting to defend or settle a fraud action. Part I of this article analyzes the potential for a successful lobbying effort, which may lead to a favorable change in governmental enforcement standards or the amicable settlement of a specific investigation. Lobbying efforts were successful in the Medicare coverage for investigational/experimental devices situation, and to a lesser extent in the partial settlement of the PATH Audits. Part II of this article examines the pro-active step of filing suit to enjoin the government from continuing a fraud investigation, and the potential barriers to such a suit posed by the Administrative Procedure Act ("APA"). Part III of this article analyzes the typical response of waiting to defend against a fraud suit and includes an analysis of some of the dispositive issues in a fraud action and the posture to be taken during an investigation. This article concludes with the determination that the most successful of the three possible provider responses is an aggressive lobbying campaign.

I. LOBBYING EFFORTS

Lobbying efforts on behalf of health care providers and their trade associations are nothing new. However, these efforts intensified at the inception of Medicare's prospective payment system in the 1980s and have continued to increase in light of the government's recent fraud enforcement efforts. For example, in the first six months of 1996, the American Medical Association ("AMA") spent $8.7 million on its lobbying efforts, second only to the tobacco giant Phillip Morris. Similarly, the American Hospital Association ("AHA") increased its lobbying efforts by seventy-four percent (to roughly $3.4 million) in the first six months of 1997, compared to $1.95 million in the first six months of 1996. Recently, in addition to their regular legislative agenda, health care providers have concentrated their lobbying efforts on reining in the government's anti-fraud initiatives.

This new "anti-anti-fraud" lobbying effort developed as a result of what is viewed by some in the health care industry as the

government's heavy-handed use of fraud investigations and enforcement. This new lobbying effort has already been quite active. In late 1997, the AHA appealed to Attorney General Reno for a moratorium on any new fraud investigations. In November 1997, the AHA created a fund to indemnify any hospital that agreed to act as a test case to fight federal fraud charges in court, rather than settling. In December of 1997, seventeen Texas lawmakers sent letters to the Department of Health and Human Services (“HHS”) Inspector General (“IG”) June Gibbs Browns, questioning that agency’s use of the False Claims Act to obtain onerous settlements from health care providers based on what could be characterized as unintentional billing errors. Also in the early stages of development is a new coalition among health care providers, tentatively named the “Health Care Accountability Partnership,” whose goal is to combat overly aggressive federal anti-fraud efforts. Organizations that have reportedly shown interest in this new partnership include the AHA, the AMA, the American Medical Group Association, and the Federation of American Health Systems. In addition, the AHA has drafted an “anti-anti fraud” bill, which was introduced in the House of Representatives in the spring of 1998. The bill is designed to limit the government’s use of the False Claims Act against providers in situations involving negligible amounts and honest billing mistakes.

This increased pressure from the private sector has prompted Attorney General Reno to defend her department's use of the fraud statutes. In 1998, she stated that "[t]hese are not cases where we are seeking to punish someone for honest billing mis-

17. See id. at 3.
takes."\textsuperscript{19} She went on to assure the health care industry that the Department of Justice would not use the False Claims Act to prosecute mere billing "errors."\textsuperscript{20} However, providers have taken little comfort from her remarks.

The intensive lobbying efforts by the industry have yielded positive results. Two successful lobbying efforts include the investigational medical devices controversy and, to a lesser extent, the PATH audits. The investigational devices controversy resulted in the government modifying its policy by extending Medicare coverage to a new class of medical devices. Although the PATH lobbying effort continues, already it has resulted in an easing of the fraud investigation for approximately one-third of the teaching hospitals that had been subjected to the probe. This section provides a deeper analysis of these two lobbying efforts.

A. Investigational Devices Lobbying Efforts

The quintessential example of a successful health care lobbying effort by providers facing a federal fraud initiative can be seen in the investigational devices controversy in 1994 and 1995. To understand this issue, it is necessary to have a basic familiarity with the underlying coverage dispute.

The Food and Drug Administration ("FDA") regulates the sale and classification of medical devices in the United States. Certain medical devices that are life-sustaining or present a risk of injury or illness to a patient, such as pacemakers and replacement heart valves, require FDA approval before they can be marketed legally.\textsuperscript{21}

The Medicare program is a government sponsored health insurance program that provides medical benefits for the aged and disabled.\textsuperscript{22} Medicare is administered by the Health Care Financing Administration ("HCFA"), which contracts with regional insurance companies (known as "fiscal intermediaries" and "carriers") to administer the Medicare program on HCFA's behalf.\textsuperscript{23} In 1977, HCFA responded to inquiries concerning Medicare reimbursement for certain medical devices lacking

\textsuperscript{19} See Reno Defends False Claims Act Use; AHA Seeks Changes in Use of Law, 7 BNA's Health L. Rep. 204 (Feb. 5, 1998).
\textsuperscript{20} See id.
FDA marketing approval. HCFA sent letters to the Medicare contractors instructing them to make coverage determinations for these devices on a case-by-case basis. Intermediaries were instructed that coverage for these investigational/experimental devices should be provided if the particular device’s usage was generally accepted in the local medical community. In general, hospitals purchase these devices from manufacturers; they are then implanted into a patient during surgery. Thus, hospitals experience a financial loss if Medicare reimbursement is precluded. The hospitals (rather than physicians) were the parties involved in this reimbursement dispute.

Medicare contractors continued to make reimbursement determinations on a case-by-case basis from 1977 to 1986. In 1986, however, HCFA amended its instructions. For the first time, it explicitly tied investigational device reimbursement to the FDA approval process. This 1986 Hospital Manual amendment excluded Medicare reimbursement for investigational devices that had yet to receive FDA marketing approval. However, hospitals continued to actively seek reimbursement for these non-FDA-approved devices. More often than not, these devices were simply new generations of older FDA-approved devices. They were actually safer and more effective than the original devices, but had yet to complete the lengthy FDA approval process. Despite the 1986 amendment, many fiscal intermediaries continued to make individual coverage determinations on a case-by-case basis between 1986 and 1994. Thus, hospitals regularly received reimbursement for these non-FDA-approved medical devices during this period.

In June 1994, the government began a nationwide investigation of 130 hospitals that had received Medicare reimbursement, primarily for non-FDA-approved investigational cardiac devices between 1986 and 1994. In its defense, the hospital industry argued that there had been considerable confusion regarding

25. See id.
28. See id.
Medicare reimbursement for these investigational devices. Many hospitals argued that the government's agent, the fiscal intermediaries, had implicitly covered such devices by continuing to reimburse hospitals for the previous eight years. Therefore, because of their good faith reliance on the fiscal intermediaries, the hospitals argued that they should not be exposed to any fraud liability. Not surprisingly, the massive fraud investigation began to have a chilling effect on the hospital industry, causing many well-known facilities to stop clinical trials involving investigational devices.

In response, the trade associations representing the hospitals and other health care providers united and appealed to Congress. They argued that the real victims of this fraud probe were the Medicare beneficiaries, who would be denied access to the latest technology as a result of HCFA's change in policy. In January 1995, a coalition of over thirty powerful organizations, including the AMA and the AHA, began a letter-writing campaign to members of Congress, pleading for Medicare coverage for investigational devices and an end to the ongoing fraud investigation. In May 1995, several California hospitals joined together and filed suit against Donna Shalala, the Secretary of HHS, in an effort to enjoin the ongoing fraud investigation. In June 1995, Senator Orrin Hatch (R-Utah) introduced a bill in the Senate aimed at reversing HCFA's 1994 decision to crack down on Medicare payments for non-FDA-approved investigational devices. A similar bill was also introduced in the House by Congressman William Thomas (R-Calif.).

The vigorous lobbying effort resulted in HCFA's announcement in September 1995 that it would change its policy regarding investigational devices. The new policy provided

---

32. See Scott, supra note 8, at 38.
reimbursement for updated versions of legally marketed, FDA-approved medical devices used in clinical trials, but continued to exclude first-of-a-kind devices that have yet to receive FDA approval. The FDA implemented a new categorization process to assist HCFA in coverage determinations. Under this new process, the FDA classified devices according to their experimental status: "experimental/investigational" (Category A) devices and "non-experimental/investigational" (Category B) devices. Category A devices are excluded from Medicare coverage, while Category B devices may be covered on a case-by-case basis by the fiscal intermediaries. The HCFA policy reversal resulted in relief for hospitals subjected to the investigational devices fraud probe and was viewed as a victory for the providers that had been lobbying for the change.

B. PATH Audits Lobbying Efforts

The PATH audits provide another example of the government revising a fraud initiative as a result of vigorous lobbying efforts by the health care community. Although the result in the PATH context has not been a complete victory for providers, several hospitals have been shielded from federal liability arising from the fraud probe. To appreciate the lobbying efforts involved, it is important to have a basic understanding of the underlying dispute.

Generally, Medicare Part A reimburses hospitals for inpatient services rendered to Medicare beneficiaries, while Medicare Part B reimburses physicians for services rendered to these beneficiaries. Private insurance companies, known as Medicare carriers, have contracted to administer Medicare Part B throughout the country on behalf of HCFA. Teaching hospitals may bill Medicare Part B for certain services rendered to Medicare beneficiaries by attending teaching physicians. However, a medical service performed by an intern alone is not separately billable to Medicare Part B, but is considered to be

37. See 42 C.F.R. §§ 405.201-209 (1998); Particular Services Excluded From Coverage, 42 C.F.R. § 411.15 (1998); Criteria for Determining that a Provider, Practitioner, or Supplier Knew that Services were Excluded from Coverage as Custodial Care or as Not Reasonable and Necessary, 42 C.F.R. § 411.406 (1998).
41. See 42 C.F.R. § 415.172; BNA's HEALTH L. & BUS. PORTFOLIO SERIES § 1600.03.
included in the teaching hospital’s reimbursement under Part A.\textsuperscript{42}

In 1969, HCFA established criteria whereby a teaching hospital could bill Medicare Part B for an attending physician’s services when the services were actually performed by an intern, as long as that intern was under the “general supervision” of the attending physician.\textsuperscript{43} This policy, enunciated in HCFA Intermediary Letter No. 372, created a vague standard that did not appear to require for reimbursement purposes the physical presence of an attending physician to supervise an intern’s actions.\textsuperscript{44} In 1992, HCFA amended this policy to state that a service would not be covered unless the attending physician was actually present when the medical service was rendered.\textsuperscript{45} Although HCFA viewed this as a clarification, providers saw this as a complete revision of the prior regulations. Some of the Medicare Part B carriers did not issue clear guidance to their providers concerning HCFA’s clarification.\textsuperscript{46} In December 1995, HCFA issued a final rule stating that an attending physician must “direct the care from such proximity as to constitute immediate availability,” in other words be “physically present,” at the administration of medical services in order to bill Medicare Part B.\textsuperscript{47} The new rule clarified the issue and eliminated the coverage criteria set forth in the 1969 intermediary letter.

In May 1996, the Medicare Carriers Manual was revised to alert teaching hospitals to this change in policy.\textsuperscript{48} A month later, the HHS Office of Inspector General (“OIG”) announced plans to investigate and audit the billing practices of all 125 academic medical institutions in the nation, an initiative that became known as Physicians at Teaching Hospitals.\textsuperscript{49} Under PATH, however, the government sought to retroactively hold the teaching hospitals accountable for the new standard. The

\begin{itemize}
  \item \textsuperscript{42} See Services of Residents in Approved GME Programs, 42 C.F.R. § 415.200 (1998).
  \item \textsuperscript{44} See BNA’s HEALTh L. & BUS. PORTFOLIO SERIES § 1600:0302.
  \item \textsuperscript{45} See Health Care Financing Memorandum FQA-541 (Dec. 30, 1992).
  \item \textsuperscript{46} See BNA’s HEALTh L. & BUS. PORTFOLIO SERIES § 1600:0303.
  \item \textsuperscript{47} See 42 C.F.R. § 415.174 (1998).
  \item \textsuperscript{48} MEDICARE CARRIER’S MANUAL, HCFA Pub. 14, Part 3, § 15016 (May 30, 1996).
  \item \textsuperscript{49} See Physician Payment: IG to Audit All Hospital Academic Institutions Under PATH, Officials Say, 5 BNA’S HEALTh L. REP. 30, at d11 (July 25, 1996).
\end{itemize}
government's rationale was that the December 1995 amendment was a mere "clarification" of the government's policy, and that teaching hospitals had notice of the standard since 1992.

A lobbying effort led by the Association of American Medical Colleges ("AAMC") and the Association of Academic Health Centers quickly mobilized against this new fraud investigation.50 In early 1996, the two associations sent letters to HHS Secretary Shalala urging the government to exercise restraint in the audits, arguing that the OIG was arbitrarily applying, retroactively to 1990, guidelines that did not go into effect until mid-1996.51 During the first six months of 1997, roughly fifty lawmakers, including Senators and Congressmen from both parties, sent letters to Secretary Shalala expressing their concern regarding the PATH initiative, and arguing that HHS was unfairly attempting to retroactively apply the "present physician" standard.52

On July 11, 1997, the government announced that it would drop sixteen of the forty-nine PATH audits underway at the time. The majority of hospitals dropped from the audits were located in New England, where the regional Medicare carrier had not thoroughly explained the reimbursement rules to the hospitals.53 The HHS General Counsel noted that "the standards for paying teaching physicians under Part B of Medicare have not been consistently and clearly articulated by HCFA over a period of decades."54 The OIG revised its guidelines concerning the PATH audits to provide that an audit would only be conducted where the Medicare carrier issued clear explanations before December 30, 1992, regarding the rules for reimbursement for the services of teaching physicians. Similarly, the OIG agreed not to initiate a new audit until it obtained carrier materials showing that clear instructions regarding reimbursement were given to the teaching physicians concerning the "physically present" standard.55

50. See Restore Trust/PATH Initiatives, 6 BNA's HEALTH L. REP. 219 (Feb. 6, 1997).
51. See id. at 220.
52. See Congressional Opposition Mounts to HHS IG's Teaching Hospital Audits, 1 BNA's HEALTH CARE FRAUD REP. 445-46 (July 16, 1997).
53. See Deanna Bellandi, Off the Hook: HHS Drops 16 PATH Audits, Cites Unclear Billing Guidance, MOD. HEALTHCARE, July 21, 1997, at 12; see also Ursula Himali, HHS Backs Off Anti-Fraud Initiative, Dropping Audits of 16 Teaching Hospitals, 1 BNA's HEALTH CARE FRAUD REP. 442-43 (July 16, 1997).
54. See Bellandi, supra note 53, at 12.
55. See Himali, supra note 53, at 442.
Because only sixteen teaching hospitals were dropped from the investigation, the initial lobbying efforts clearly were not a complete victory for the teaching hospitals, and these efforts continued. On October 21, 1997, the Labor, Health and Human Services, and Education Subcommittee of the Senate Appropriations Committee held a hearing addressing the OIG's nationwide PATH initiative. At that hearing, AAMC President Jordan Cohen pleaded with lawmakers to suspend the remaining PATH audits, arguing that the facilities should not be held to standards that were not clearly articulated. Additionally, Representative Bill Thomas (R-Calif.) called for the General Accounting Office ("GAO"), the investigative arm of Congress, to report on the PATH audits. Subsequently, the full House voted for the GAO to conduct the audit of the PATH investigations. The GAO's report, released on July 23, 1998, reviewed the OIG's legal authority to investigate the PATH situation and the OIG's approach to and methodology for conducting the audits.

The GAO report concluded that the OIG had the authority under the False Claims Act to investigate teaching hospitals' Medicare billing for services provided by interns and attendings, but it vigorously criticized the OIG's investigative techniques. The GAO questioned the OIG's intent to audit every major teaching hospital and suggested that the OIG adopt a new approach to determine which facilities to audit so that it could more wisely focus its resources. The GAO also determined that the OIG exaggerated the extent of the billing problems uncovered at several teaching hospitals.

While these lobbying efforts were underway, on October 29, 1997, several major teaching hospitals and medical associations had grown impatient with the progress on the lobbying front. They filed suit against Secretary Shalala in the federal district court in Los Angeles seeking declaratory and injunctive relief. The suit was dismissed in April 1998. The district court held that the case was not ripe because the plaintiffs failed to comply

56. See Path Hearings, 6 BNA'S HEALTH L. REP. 1665 (Oct. 30, 1997).
58. See Gardner, supra note 57, at 12; see generally GAO Reviews PATH Audits, 7 BNA'S HEALTH L. REP. 131 (Jan. 22, 1998).
60. See id.
with the Administrative Procedure Act ("APA"). The case is currently on appeal to the Ninth Circuit.

While the PATH audit controversy continues, a bill introduced into the House in March 1998 may affect the outcome of the PATH audits as well as many other governmental fraud investigations. Representatives Bill McCollum (R-Florida) and Bill Delahunt (D-Mass.) introduced "The Health Care Claims Guidance Act," aimed at amending the civil False Claims Act ("FCA"). If passed, this bill would preclude the government from prosecuting health care providers for honest billing mistakes, and potentially decrease the overall activity in health care fraud enforcement. The bill, which was backed by the American Hospital Association, has forty-seven co-sponsors. The AHA and the bill's supporters have argued that the government is abusing the civil FCA in order to fight fraud and abuse. AHA president Dick Davidson stated, "Under the Justice Department's tactics hospitals and health systems are presumed guilty until proven innocent." He also noted that "[m]ost Medicare billing errors are due to conflicting, complex governmental regulations covering Medicare."

The current form of the bill imposes a de minimis standard on Medicare overpayments. If the overpayment is less than a certain percentage (to be determined by HHS) of the provider's total Medicare reimbursement, the provider is liable only for the amount of the overpayment plus interest, without additional penalties. Moreover, providers who rely upon fiscal intermediary or carrier advice are liable only for the overpayment plus interest. The bill also raises the burden of proof under the FCA from a preponderance of the evidence standard to a clear and convincing evidence standard. Additionally, facilities that installed an effective corporate compliance program would reduce their potential exposure under the civil FCA, facing only actual

---


62. See H.R. 3523; see also Legislation Changing FCA to Ease Up on Hospitals Introduced in House, 2 BNA'S HEALTH CARE FRAUD REP. 203-04 (Mar. 25, 1998).

63. See H.R. 3523.

64. See Legislation Changing FCA to Ease Up on Hospitals Introduced in House, supra note 62, at 203.

65. See id.

66. See id. at 204.
damages plus interest, rather than treble damages plus $5,000 to $10,000 per claim.67

On June 3, 1998, the Department of Justice ("DOJ") issued a guidance to all of its field attorneys concerning the application of the FCA against health care providers.68 The guidance was issued as a result of the intense lobbying effort against the DOJ usage of the FCA concerning the PATH and other nationwide fraud initiatives. The threatened passage of the Health Care Claims Guidance Act may have played a role in the issuance of the DOJ's guidance.

The DOJ guidance was issued to promote consistent enforcement of the FCA and to avoid a rigid approach that fails to recognize the particular facts and circumstances of an individual case.69 The guidance directs Assistant United States Attorneys to evaluate whether the provider (1) submitted false claims to the government, and (2) knew its claims were false.70 Assistant United States Attorneys are instructed to conduct a multi-step analysis before alleging an FCA violation. On the first step they are to: examine relevant statutory guidance; verify the accuracy of the data and evidence; and conduct an investigation. On the second they are to: consider whether the provider had been given prior notice concerning the illegality of its practices; consider the clarity of the underlying reimbursement rule or policy; weigh the magnitude and pervasiveness of the false claims; consider mitigating factors and compliance plans; consider any prior remedial efforts; analyze the guidance issued by the government or its agents (i.e. intermediaries, carriers); consider prior audits; and consider other information on provider's "state of mind."71

The June 3, 1998, guidance was viewed as a step in the right direction by the health care industry. It resulted in an easing of congressional pressure concerning the Health Care Claims Guidance Act.72 One of the bill's co-sponsors, Rep. William Dela-
hunt, withdrew his support as a direct result of the guidance. 73
While the bill is still pending, its demise is highly likely; never-
theless, its introduction illustrates the power of the health care
industry in Washington.

II. FILING SUIT AGAINST THE GOVERNMENT

Faced with a potential investigation of practices they previ-
ously believed were permissible, some health care providers
have chosen to sue the federal government to enjoin the fraud
investigation. This measure may be viewed as a form of collat-
eral attack against the government's use of the fraud and abuse
laws, independent of continuing lobbying efforts. Often these
providers grow frustrated with the progress on the lobbying
front, and instead seek a quick judicial resolution to the invasive
fraud probe.

For example, while the investigational devices controversy
was playing out in Washington in May 1995, twenty-five Califor-
nia hospitals, led by Cedars-Sinai Medical Center, sued HHS
Secretary Shalala seeking to enjoin her department's investiga-
tional devices fraud probe. 74 Similarly, in October 1997, the As-
sociation of American Medical Colleges sued to enjoin the
ongoing PATH investigations. The suit was dismissed by the dis-
trict court, and is currently pending appeal to the Ninth Cir-
cuit. 75 In addition, in October 1996 the Ohio Hospital
Association and the AHA filed suit against Secretary Shalala,
seeking to enjoin a fraud investigation targeting alleged labora-
tory billing abuses, known as the Ohio Hospital Project. 76 Gen-
erally, these suits have not succeeded, largely due to barriers
posed by the APA, which requires parties to exhaust their ad-
ministrative remedies prior to filing a lawsuit. In general, lobby-
ing efforts appear to have produced a better outcome for
providers than the lawsuits filed against the government.

The idea of providers suing the Secretary of HHS to enjoin a
governmental action is not new. In the 1980s, the AHA brought
several suits against the Secretary seeking to enjoin actions that
adversely affected provider reimbursement. 77 These suits dealt

73. See id.
74. See Cedars-Sinai, 939 F. Supp. at 1459.
75. See Association of Am. Med. Colleges, CV-98-01734-CM (C.D. Calif.), dis-
missed July 9, 1998; appeal docketed, No. 98-56190 (9th Cir. July 17, 1998).
77. See American Hosp. Ass'n v. Schweiker, 721 F.2d 170, 172 (7th Cir. 1983);
American Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1043 (D.C. Cir. 1987); American
with issues such as the Hill-Burton Act, the peer review organization program, the Medicare secondary payer provisions, and the medical malpractice premium reimbursement issue. These cases achieved only moderate success, again largely due to the barriers posed by the APA. Although a discussion of the specific issues involved in these lawsuits is beyond the scope of this article, these cases are instructive in that the analysis applied to present-day suits is the same as applied to these cases from the 1980s.

These provider-initiated suits often turn on the courts' interpretation and application of the APA. The APA requires an agency to publish proposed rules and allow for a period of public consideration and comment. However, this notice and comment period requirement applies only to substantive rules. An agency does not have to comply with the notice and comment procedure when issuing "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice..." Generally, HCFA's policy revisions, manual updates, intermediary letters and directives have been viewed as interpretive rules, and therefore not subject to challenge on the ground that the agency failed to comply with notice and comment procedures.

A. Cedars-Sinai (Investigational Devices) Suit

The Cedars-Sinai case challenging the investigational devices fraud probe resulted in a victory for the California hospitals at the district court level. The hospitals sued in May 1995, seeking a declaratory judgment and injunctive relief against the investigational devices initiative. They alleged that the 1986 Medicare manual revision, which denied Medicare reimbursement for non-FDA-approved investigational devices, was unlawful because it was not promulgated in accordance with the rule-making requirements of the APA. The hospitals sought to invalidate the 1986 policy revision and to enjoin the Secretary from


enforcing the amended policy, putting an end to the fraud probes.\textsuperscript{82}

The trial court invalidated the 1986 HCFA revision after finding that it was a substantive rule and not promulgated in accordance with the requirements of the APA. The court reasoned that the 1986 revision withdrew coverage for a benefit that had been previously provided, that is, coverage of investigational devices. The revision created a new coverage exclusion, changing the existing rules and affecting beneficiaries’ rights. Therefore, the 1986 amendment was a substantive rule subject to the notice and comment period.\textsuperscript{83} Because HCFA admitted that it did not comply with the notice and comment requirement, the court ruled in favor of the hospitals and invalidated the 1986 coverage exclusion. In April 1996, the court issued a declaratory judgment and an injunction, effectively halting the ongoing investigation in that district.\textsuperscript{84}

However, the providers’ victory was short-lived. In September 1997, the United States Court of Appeals for the Ninth Circuit declined to affirm the district court’s holding and remanded the entire case.\textsuperscript{85} On appeal, the Secretary argued that the hospitals’ claims were barred by the six-year statute of limitations; that is, although the amendment was made in 1986, the hospitals did not bring suit until 1995.\textsuperscript{86} Further, she argued that the general six-year time period for commencing an action against the United States applied to judicial review of agency regulations under the APA.\textsuperscript{87} The hospitals responded that their action did not accrue until 1994, when the Secretary began the investigational devices fraud probe. The Ninth Circuit declined to address the underlying merits, and instead remanded the entire case for a factual determination on the statute of limitations issue.\textsuperscript{88} As of the date of this writing, the district court has not ruled on the case since being remanded.

\textsuperscript{82} See Cedars-Sinai, 939 F. Supp. at 1459.
\textsuperscript{83} See id. at 1465.
\textsuperscript{84} See id.
\textsuperscript{85} See Cedars-Sinai Med. Ctr. v. Shalala v. Qui Tam Relator, 125 F.3d 765 (9th Cir. 1997).
\textsuperscript{86} See id. at 769.
\textsuperscript{87} See generally 28 U.S.C. § 2401(a); Wind River Min. Corp. v. United States, 946 F.2d 710, 713 (9th Cir. 1991).
\textsuperscript{88} See Cedars-Sinai, 125 F.3d at 771.
B. Ohio Hospital Association (Lab Bundling) Suit

A suit by several Ohio hospitals has been even less successful than the Cedars-Sinai case. The Ohio case was prompted by the "Ohio Hospital Project" billing probe, a cooperative effort between state and federal enforcement authorities seeking to identify false claims resulting from billing for hospital clinical laboratory tests. The probe, which began in June 1995, sought to identify instances where a laboratory "unbundled" the billing of the tests it performed. Generally, Medicare reimbursement is greater if a lab bills individually for tests performed than if it bills for pre-established groups or "bundles" of tests. This process is known as "unbundling." The government argued that certain tests should have been bundled together, which would have resulted in lower Medicare reimbursement rates. In response, the hospitals argued that they were never instructed on certain bundling requirements and on other requirements, they were not informed until June 1994, and that the government was unfairly applying the bundling requirement retroactively to 1989. The providers argued they had no indication they were doing anything wrong, particularly because the regional Medicare intermediary regularly reimbursed them for these unbundled test bills.

In October 1996, the Ohio Hospital Association, along with the AHA, filed suit seeking injunctive and declaratory relief against the billing probe. They also sought a declaratory judgment ruling that the hospitals could not be held liable under the False Claims Act for these billings. However, the district court held that it had no jurisdiction to hear the case because the providers had failed to exhaust their administrative remedies as required by the Medicare Act.

Generally, courts are wary of lawsuits in which the parties have not gone through the entire administrative process estab-

---

90. See Five Ohio Hospitals Pay $2.3 Million to Settle Lab Billing Fraud Allegations, 5 BNA'S HEALTH L. REP. 1054 (July 11, 1996).
91. See id.
93. See id.
95. See id. at 742.
lished by the relevant statute. 96 The Social Security Act explicitly provides that:

No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under [the Medicare Act] . . . . 97

"Any individual, after any final decision of the [Secretary] made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action . . . ." 98 Courts have held that a claim arising under the Medicare Act cannot be heard in federal court until the Secretary reaches a final decision on the issue. 99 Applying this principle, the district court refused to extend equitable jurisdiction to the providers, holding that this dispute arose under the Medicare Act and that the Secretary had yet to reach a final decision on the matter. 100

However, the district court sympathized with the providers' plight, and characterized the Secretary's approach in this investigation as "heavy-handed." 101 The court suggested that the providers might eventually obtain judicial review by "calling the Secretary's bluff" and refusing to settle, thereby allowing a jury to decide whether the defendants had the requisite mental state to support a fraud conviction. 102 The court acknowledged that this route to judicial review is "extremely onerous," stating that "despite the very real possibility that the Secretary's position regarding the hospital's billing practices is wrong, the practical barriers of challenging the Secretary leave the hospital with little choice and no bargaining room." 103 In December 1997, the providers filed an appeal, which has yet to be heard. 104

In general, these provider-initiated cases have not gained any relief for the health care providers under investigation. Often

100. See Ohio Hosp. Ass'n, 978 F. Supp. at 741.
101. See id. at 742.
102. See id; see also infra, part III.
they are regarded as a mere symbolic gesture by the industry, a futile attempt to halt what is viewed as an unfair interpretation and enforcement action. As demonstrated by the PATH and investigational devices disputes, providers achieve much more success when they lobby the government.

III. WAIT AND SEE: DEFENDING A FRAUD SUIT

The option of last resort for a health care provider facing a fraud investigation is to remain in a defensive posture and litigate any resulting fraud action. As the judge in the Ohio Hospital Association case acknowledged, this is an onerous route to judicial review, but often it is the only option available. This route can be treacherous to the health care provider. The potential liability is tremendous if the government successfully proves its case. Penalties for fraudulent activities include monetary damages, exclusion from federal health care programs, state licensure sanctions, and sanctions for misdemeanor and felony convictions, including imprisonment. Because the potential liability may be too great for many health care providers, they may be forced to settle, even when the providers believe they did nothing wrong.

The highly regulated environment of the health care industry can lead to multiple interpretations of the thousands of regulations governing provider reimbursement, as seen in the PATH audits, the investigational devices dispute, and the lab test bundling disputes previously discussed. These conflicting interpretations often go to the heart of the dispute; therefore, it is not surprising that the fact finder’s intent determination is frequently the dispositive issue in a fraud action. Thus, fraud prosecutions usually turn on the government’s ability to prove the provider’s intent.

As a former prosecutor, this author would like to make a few recommendations to health care providers facing a fraud investigation and potential indictment. The posture taken by a potential defendant should be an aggressive one, and the provider should try to keep open a line of communication with the prose-

107. See Scienter is Key in Defending Accusations of FCA Violations, 1 BNA’s HEALTH CARE FRAUD REP. 315-16 (May 21, 1997).
108. See id.
cutor. Take any available opportunity to argue the merits of the case to that individual. Try to convince the prosecutor that he is wasting his time, and that the potential defendant was simply relying upon a reasonable interpretation of a complex regulation or governmental communication when he submitted the claims. Similarly, a provider would be well-advised to build a case file, and perhaps even conduct its own investigation to document support for the practices. Did the carrier or intermediary make any communications that could be used to justify the provider's billing practices? Was every other provider in the region billing in the same manner?

Finally, the provider should present all favorable evidence to the investigating official or potential prosecutor before indictment. Do not hold anything back. It is much easier for a defendant to obtain a favorable result early in the investigation and screening phases, as opposed to later in the process. The criminal justice system tends to gather momentum as it progresses, especially after indictment. The provider should attempt to convince the prosecutor that his time would be better served going after another provider who clearly committed fraud. The provider may argue that, due to its reasonable reliance upon a valid interpretation of a complex or ambiguous regulation, it lacked the requisite mental state for a conviction.

The following is an analysis of the fraud statutes most often employed by the government in the prosecution of health care providers. Specifically, this section will analyze the False Claims Act (both civil and criminal), the Federal Healthcare Programs Fraud Act, and the False Statements Act.¹⁰⁹ Particular attention will be given to the applicable knowledge requirement of each statute, because this element is often disputed in health care fraud prosecutions.

A. The Civil False Claims Act (31 U.S.C. §§ 3129-3130)

To prosecute civil fraud, the government primarily uses the civil False Claims Act ("FCA").¹¹⁰ The FCA has become one of the major enforcement tools used against health care fraud today. The FCA was originally enacted during the Civil War to prevent the government from being defrauded by defense con-


tractors.111 The original FCA was amended in 1872 to separate the civil and criminal provisions.112 The civil act was substantially revised in 1986, when Congress lowered the standard for proving intent and increased the penalties and damages provisions.113 Until the early to mid-1990s, the FCA was primarily used against defense contractors. Because of the heightened enforcement of health care fraud, the majority of cases concerning the FCA are now in the area of health care fraud.114

The civil FCA prohibits any person from knowingly presenting or causing to be presented to an officer or employee of the government a false or fraudulent claim for payment or approval.115 The damages provisions attached to this statute are quite substantial. They include a mandatory penalty of not less than $5,000 and not more than $10,000 per false claim submitted, which can add up very quickly. The act also provides for treble damages for the injury sustained by the government as a result of the false claim submitted.116 For example, if a lab billed Medicare for several individual laboratory tests when the regulations mandate bundling of the tests, each fraudulent claim filed could be subject to a $5,000 to $10,000 fine. If the laboratory submitted ten such claims a day, over ten days the statutory penalty alone could be as much as $1 million. These damages provisions are so onerous that many providers cannot risk losing a trial. More often than not, the FCA is used by the government to convince providers to settle.

1. “Knowingly” requirement

The civil FCA has always required a showing that the defendant’s actions were undertaken knowingly, although this requirement was not defined prior to 1986.117 In the 1986 amendments, Congress defined “knowingly” to mean that a person “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in

114. See Four of Five Top Qui Tam Recoveries in 1996 in Health Care Industry, Group Says, 1 BNA's HEALTH CARE FRAUD REP. 122-23 (Feb. 26, 1997).
116. See id.
117. See id.
reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.”

Although the knowledge requirement may have been lowered, the government must still make an affirmative showing of some intent. It is important to note that the FCA was not intended to hold someone liable for a mere “innocent mistake,” but is instead concerned with ferreting out “wrongdoing.”

The knowledge element is a subjective question of fact, the resolution of which can often lead to unpredictable results at trial, depending upon the fact finder’s analysis of the evidence and interpretation of the statute. However, the case law does provide some guidance as to how courts have dealt with this standard.

One case that is instructive is United States v. Krizek. In Krizek, the government contended that a certain CPT (reimbursement) code used by the defendant psychiatrist required forty-five to fifty minutes of “face to face” contact with the patient. The defendant testified that it was his impression that the fifty-minute requirement included physician preparation and staff consulting time, resulting in only perhaps twenty minutes of “face to face” time. The defendant presented credible experts who testified that his usage and interpretation of the CPT code was common practice among psychiatrists in the Washington, D.C., area. The court found that the CPT code itself did not use the specific term “face to face” and that the requirement was ambiguous. Thus, the Court found that “the government’s position on this issue is not rational and has been applied in an unfair manner in the medical community . . . .” The Court refused to impose FCA liability based upon such a “strained interpretation” of CPT codes, and found that the government’s theory of liability was plainly unfair and unjustified.

119. See Wang ex rel. United States v. FMC Corp., 975 F.2d 1412, 1420 (9th Cir. 1992).
122. See id. at 9.
123. Id. at 10.
124. See id. It should be noted that Dr. Krizek was ultimately found liable under the FCA; the court held that Dr. Krizek acted in “reckless disregard of the truth or falsity of the information” by failing to supervise his assistants’ billing procedures. For example, he allowed his subordinates to assume that he spent a full fifty minutes
stands for the proposition that there should be no civil FCA liability when the law or regulatory guidance is vague or ambiguous, and the provider acted reasonably and was unaware of the government's interpretation of the law.

Providers defending against a FCA action should vigorously litigate the knowledge element. They might successfully defend a FCA suit if the government relied on an irrational interpretation of a reimbursement regulation or rule that was never communicated to the provider. The government might have difficulty showing that a defendant knowingly submitted false claims if the underlying reimbursement policy was ambiguous or ill-defined, as in *Krizek*.

2. Presented or caused to be presented a claim for payment or approval to an officer or employee of the United States

The second element of a civil FCA violation is that the defendant presented or caused to be presented a claim for payment or approval to an officer or employee of the United States Government. The act defines a claim as "any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded . . . ."126

There are few reported cases addressing this "claim presented" element of the FCA. Courts typically look to the plain language of the underlying statute or authority for which the defendant seeks payment to determine whether a claim has been presented.127 In a health care fraud case, whether the provider presented a claim for payment, such as a Medicare bill, is a factual determination.

The second element is the submission "to an officer or employee of the United States Government."128 Clearly, whether the provider billed the government is also a factual determination. The government can prevail on a FCA violation even though a third party (i.e., the regional fiscal intermediary or car-

---

on each patient's case (the most lucrative CPT) unless he stated otherwise, never reviewed bills, and often billed for twenty hours of work in a twenty-four-hour day. He was found liable for these sloppy procedures.

126. Id. at § 3729(c) (1998).
rrier) actually received, administered and paid the claims submitted by the defendant. Typically, federal courts hold that the federal government is the real party in interest when such a false claim is submitted to a contractor because federal funds ultimately pay for the submitted claims. Therefore, providers have little chance of success in arguing that they only submitted a claim for payment to the fiscal intermediary and not directly to the federal government.

3. Claim is false or fraudulent

The third and final element of the FCA requires that the claim must be “false or fraudulent.” The majority of cases in this area involve the submission of claims that are egregiously false, such as when a physician seeks reimbursement for a service that was never performed. Another common example of false claims is DRG or CPT “upcoding,” where a physician bills Medicare or Medicaid for a more serious procedure than actually performed, resulting in excessive reimbursement. Falsification of Medicare or Medicaid cost reports is also common. To determine whether a claim is false often requires an objective analysis of the evidence presented at trial. For example, a claim is clearly false if a physician bills Medicare for an office visit that never took place.

B. Criminal False Claims Act (18 U.S.C. § 287)

Because the elements of the civil and criminal FCA are basically the same, courts liberally apply precedent governing one statute to cases arising under the other. Additionally, if the government is successful in obtaining a criminal conviction, the

129. See, e.g., Peterson v. Weinberger, 508 F.2d 45 (5th Cir. 1975).
130. See id. at 51-52.
133. See Krizek, 859 F. Supp. at 7.
defendant is then collaterally estopped from re-litigating the substantive issues in a subsequent civil FCA action. 136

The criminal False Claims Act was enacted at the same time as the civil False Claims Act and has essentially the same elements. 137 The only difference is that in the criminal statute requires a more culpable mental state. For example, the United States Court of Appeals for the Fifth Circuit recently upheld the following jury instruction for a criminal FCA violation:

"knowingly" "means that the act was done voluntarily and intentionally and not because of mistake or accident." "Willfully" or "willingly" was defined to "mean that the act was committed voluntarily and purposely, with the specific intent to do something the law forbids—that is to say, with bad purpose either to disobey or disregard the law." 138

Not all circuits require that such a high level of intent be proved for a criminal FCA conviction. For example, some circuits have endorsed a conscious avoidance jury instruction. 139 In United States v. Nazon, the Seventh Circuit affirmed the use of a conscious avoidance or deliberate ignorance jury instruction. 140 Dr. Nazon was convicted of criminal FCA violations because he billed Medicaid for the services of physician assistants who were not present during procedures, and impermissibly billed for lab tests he did not perform. At trial, Dr. Nazon testified that he had never read the Medicaid provider manual, and that he simply had billed what he thought he deserved. 141 The Seventh Circuit upheld his conviction, holding that the conscious avoidance jury instruction was proper in that case because the defendant deliberately avoided familiarizing himself with the rules and conditions of the Medicaid program. 142 The jury was able to infer the defendant’s guilty knowledge from the surrounding facts and circumstances, including the fact that Nazon had been told repeatedly that he was billing incorrectly. The trial court instructed the jury that "[i]f you find that a person had a strong suspicion that things were not what they seemed or that some-

136. See United States v. Thomas, 709 F.2d 968, 972 (5th Cir. 1983); see also Hudson v. United States, 118 S. Ct. 488, 495-96 (1997) (bank fraud case discussing when dual prosecution under criminal and civil statutes constitutes double jeopardy).

137. See 18 U.S.C. § 287; see also United States v. Okoronkwo, 46 F.3d 426, 430 (5th Cir. 1995) (showing elements in tax fraud case).


139. See United States v. Nazon, 940 F.2d 255, 259 (7th Cir. 1991) (Manion, J.).

140. See id. at 259.

141. See id. at 257.

142. See id. at 260.
one had withheld some important facts, yet shut his eyes for fear of what he would learn, you may conclude that he acted 'knowingly' . . . ."143

Because the intent requirement of the criminal statute requires a higher level of knowledge than the civil statute, the government will have greater difficulty proving a provider's culpability if the government relies on a questionable and perhaps even retroactive application of a reimbursement rule or regulation. This was arguably the case in the PATH audits, laboratory bundling disputes, and investigational devices disputes.

C. The Medicare and Medicaid Fraud Statute
(42 U.S.C. § 1320a-7b(a))

The Medicare and Medicaid Fraud Act, enacted in 1977, is intended to punish providers for false statements they make in connection with applications for payment under any federally funded health care program.144 While the civil or criminal FCA and the False Statements Act145 are intended to protect the integrity and fiscal soundness of all government programs, the Medicare and Medicaid Fraud Act is intended to protect against fraud only in federal health care programs.146 Surprisingly, there are few reported cases involving this statute. Instead, federal prosecutors appear to have used traditional fraud statutes, such as the FCA and the False Statements Act, to prosecute Medicare and Medicaid fraud. The Medicare and Medicaid fraud statute contains three elements: (1) knowingly and willfully; (2) making or causing to be made a false statement or representation of material fact; and (3) in a claim for payment under any federal health care program.147

1. Knowingly and willfully

Unlike the civil FCA, the knowledge element of this statute is defined as "knowingly and willfully."148 Courts have interpreted

143. Id. at 258.
144. See 42 U.S.C. § 1320a-7b(a) (1998). The Medicare/Medicaid False Statements Act was passed at the same time as the subsection directly preceding, the Anti-Kickback Statute, 42 U.S.C. § 1320a7b[b], another statute often used by the government in fraud enforcement.
145. See 18 U.S.C. § 1001 (1998); see also infra section III(D).
147. See id.; see also United States v. Laughlin, 26 F.3d 1523, 1526-27 (10th Cir. 1994).
this language to mean that the government must prove the defendant made a false material representation in an application for a benefit, and that the defendant actually knew at that time that the claim or representation he was submitting was false.\textsuperscript{149} \textit{United States v. Laughlin} provides a helpful illustration of the knowledge requirement. Dr. Laughlin was a physician who fraudulently billed Oklahoma Medicaid both for procedures performed and for procedures he did not perform. The Tenth Circuit reversed Laughlin's fifty-two count conviction under 42 U.S.C. section 1320a-7b(a)(1), because the jury was improperly instructed.\textsuperscript{150} The court held that the jury instruction was insufficient because it failed to inform the jury that the "statement must not only be false but that Dr. Laughlin must also have \textit{known that the statement was false when the claim was submitted}."\textsuperscript{151} This standard holds the government to a higher level of proof, in which the government must prove that the defendant knew he was violating the rules of the program.

Another example of such a case is \textit{United States v. Larm}.\textsuperscript{152} Dr. Larm was convicted of billing Hawaii Medicaid for physician "office visits," although he personally neither saw the patients nor rendered services.\textsuperscript{153} Additionally, Larm frequently upcoded and billed for more extensive services than were actually performed. As in \textit{Laughlin}, the \textit{Larm} court held that the government must prove that the defendant specifically knew he was making a false statement or representation in application for payment.\textsuperscript{154} Unlike in \textit{Laughlin}, however, the government in \textit{Larm} had objective evidence indicating Larm's knowledge. Significantly, Larm twice had been told by a representative of the carrier that he was using the wrong codes. The court also emphasized the fact that the two codes Larm was manipulating were specifically defined. They were listed on the same page in the Medicaid Manual, which had been provided to Larm. The court also relied on the warnings and the availability of the correct information from the Medicaid Manual to demonstrate

\begin{flushright}
\textsuperscript{149}. \textit{See Laughlin}, 26 F.3d at 1526; \textit{see also} United States v. Larm, 824 F.2d 780, 783 (9th Cir. 1987).
\textsuperscript{150}. \textit{See Laughlin}, 26 F.3d at 1529.
\textsuperscript{151}. \textit{Id.} at 1526 (emphasis added).
\textsuperscript{152}. \textit{See Larm}, 824 F.2d at 780.
\textsuperscript{153}. \textit{See id.} at 782.
\textsuperscript{154}. \textit{See id.} at 783.
\end{flushright}
Larm's knowledge; as a result, the court affirmed the conviction.\textsuperscript{155}

Therefore, it appears that the Medicare and Medicaid fraud statute requires the government to prove that the defendant knew he was unlawfully billing Medicare. This burden of proof may be difficult for the government to meet if applied to any of the factual scenarios discussed in detail in this article. For example, if the government fails to notify providers of the proper lab test bundling rules, the government may subsequently have difficulty proving that a provider knowingly violated those rules. The same would be true if the government attempted to hold the teaching hospitals retroactively liable under the "present physician" standard when the providers were never informed of the policy change.

2. Making or causing to be made a false statement or representation of material fact

The second element of the Medicare and Medicaid fraud statute is making or causing to be made a false statement or representation of material fact.\textsuperscript{156} Much of the case law under this statute has addressed the knowledge element. However, the reported cases have been silent regarding the other elements, including this "materiality" requirement. In cases involving similar fraud statutes, the Supreme Court has held that the materiality requirement is a mixed determination of law and fact for a jury to decide.\textsuperscript{157} In determining whether a statement or representation is material, the key issue is whether the statement has "a natural tendency to influence" a determination by the other party.\textsuperscript{158} For example, coding information (i.e., CPT or DRG codes) included in a Medicare bill would likely be deemed a material representation, because the information has a natural tendency to influence the Medicare carrier or fiscal intermediary either to pay the bill or to deny reimbursement.

\begin{footnotes}
\item[155.] See id. at 780.
\item[156.] See 42 U.S.C. § 1320a-7b(a)(1) (1998); see also Laughlin, 26 F.3d at 1528.
\item[158.] United States v. Brown, 763 F.2d 984, 993 (8th Cir. 1985).
\end{footnotes}
3. Claim is made to a federally funded health care program

The third element under this statute is that a claim for payment be made under a federal health care program. Any health care program that is funded in part by federal funds qualifies as a federal health care program. Such programs include Medicare, Medicaid and CHAMPUS. This element is easily established.


Unlike the Medicare and Medicaid fraud statute, the False Statements Act is intended to prevent fraud in all government programs, not just in health care programs. However, the two statutes have similar elements, including the same intent requirement (knowingly and willfully) and a requirement that the false representation be material. The False Statement Act was originally passed in 1863 as part of the original FCA. The statute is a wide-reaching prohibition against government fraud, and the courts have interpreted its language broadly. As the Fifth Circuit explained, “[t]he false statement statute is necessarily couched in very broad terms to encompass the variety of deceptive practices which ingenious individuals might perpetrate upon an increasingly complex government.” The elements of the False Statements Act are (1) knowingly and willfully; (2) making a false statement, concealing a material fact, or using a writing or document that is false in a material matter; and (3) in any matter within the jurisdiction of any department or agency of the United States.

1. Knowingly and willfully

The False Statements Act requires that the defendant acted knowingly and willfully. Most courts require a showing that the defendant acted “with knowledge” when he or she made the false statement or representation. This means that there must be some evidence that the defendant knew the statement was false at the time it was made. However, some courts have

161. See United States v. Massey, 550 F.2d 300, 305 (5th Cir. 1977).
163. Id.
164. See, e.g., United States v. Markham, 537 F.2d 187, 194 (5th Cir. 1976) (case concerning patent concealment).
held that the intent required to commit this crime may be proved by evidence of conscious avoidance or reckless disregard in learning of the truth, thus allowing analogies to be drawn to the intent required under the civil FCA. For example, the Fifth Circuit has held that a conviction requires proof that the defendant had the specific intent to make a false or fraudulent representation "deliberately or at least with reckless disregard of the truth and with the purpose to avoid learning the truth." This is somewhat surprising in light of the fact that the statute reads "knowingly and willfully." Although the language in the False Statements Act is similar, the Medicare fraud statute requires a more culpable mental state.

Federal circuit courts have affirmed the use of the conscious avoidance and reckless disregard standard in False Statements Act cases. For example, in *United States v. Evans*, the defendants were convicted for submitting fraudulent Medicare claims. The defendants owned a medical services supply company. While leasing equipment to Medicare beneficiaries, the defendants had the patients sign blank Medicare reimbursement forms. During the course of the lease, the company filled out the signed blank forms for services beyond the lease agreement and submitted those claims for reimbursement, even though no actual additional services were rendered. The appellate court affirmed Evans' conviction, holding that "[t]he misrepresentation must have been made deliberately, knowingly, and willfully, or at least with reckless disregard of the truth and with a conscious purpose to avoid learning the truth."

Under this approach, the knowledge required for a violation under the False Statements Act is very similar to the standard required under the civil FCA. The government must produce evidence that shows the defendant acted in reckless disregard of the truth. Evans clearly violated the Medicare provider regulations by having beneficiaries sign blank forms and billing for services not rendered. It is important to note that in this case the government had facts to prove the defendant's knowledge. However, in the fraud scenarios previously discussed, the gov-

167. *See* United States v. Evans, 559 F.2d 244 (5th Cir. 1977).
168. *See id.*
169. *Id.* at 246 (quoting United States v. Lange, 528 F.2d 1280, 1288 (5 Cir. 1976)).
ernment may fall short in showing that any of the providers acted in reckless disregard of the truth, because the "truth" was ambiguous and standards were not clearly communicated to the provider.

2. Making a false statement, concealing a material fact, or using a writing or document that is false in a material matter

The second element of the False Statements Act is the making of a false statement, concealing a material fact, or using a writing or document that is false in a material way. The portion of this element that would most concern a health care provider defending a fraud action would be the "making" of a false material statement or writing. A provider may argue that the Medicare bills submitted were not clearly "false" because the government's policy was ambiguous and ill-defined. Such an argument could be made, for example, in the PATH situation or the lab test bundling scenario. Courts have held that, if it is difficult to determine whether the statements were false, the "government [has] the burden to allege and prove that the statements were false under any reasonable interpretation." In light of the tremendous confusion surrounding these rules and regulations, the government may have difficulty proving that a provider's interpretation was unreasonable.

Additionally, the false statement must be a material representation. As discussed above, the Supreme Court recently held that the question of materiality is a mixed question of law and fact that should be put to the jury. If the information in question has "a natural tendency to influence, or be capable of affecting or influencing, a government function," then such a representation would be material. Thus, representations made in a Medicare bill should be deemed material if they affect the decision of the carrier to pay the claim.

3. In any matter within the jurisdiction of any department or agency of the United States

The third and final element of the False Statements Act is that the false statement must be made in a manner within the juris-

171. United States v. Adler, 623 F.2d 1287, 1289 (8th Cir. 1980).
172. See Gaudin, 515 U.S. at 512.
diction of a department or agency of the United States.174 This language has been construed broadly by the federal courts, and the phrase has been given a “non-technical meaning in order to accomplish the purpose of the statute.”175 Courts also have held that as long as the money used came from federal funds, the false statement will be considered within the jurisdiction of a department or agency of the United States.176 It need not be proved that the defendant knew federal monies were involved. Therefore, it should not be difficult for the government to establish this element of the False Statements Act, as long as any portion of the questionable claims was paid with federal money.

CONCLUSION

The increased governmental scrutiny of alleged “fraud and abuse” by health care providers has dramatically changed the environment of the health care industry. It has become commonplace for the government to launch nationwide investigations of entire sectors of the health care industry. Providers often feel that they will be coerced into multi-million dollar settlements by the government’s threatened use of the FCA, a cause of action that a provider cannot afford to lose at trial. This situation has left providers in a quandary about what they can do to avoid an unfavorable outcome. In many cases, providers may believe that their billing practices have been lawful and have been sanctioned by the government and its agents for years.

A few providers have begun to combat what they feel is the government’s illogical interpretation of the law and heavy-handed use of the fraud statutes. The options available for such a provider are lobbying for a governmental policy change, suing the government to enjoin the unjustified enforcement, or sitting back and eventually defending against a fraud action. As demonstrated by the cases discussed above, the most successful option appears to be an aggressive lobbying campaign, which may lead to a favorable result for the investigated provider, and perhaps the entire industry.

175. Massey, 550 F.2d at 305.
176. See United States v. Baker, 626 F.2d 512, 514 (5th Cir. 1980).